Food and Drug Administration, HHS

- (2) With respect to pleadings, at the time specified in §12.96(a) for the filing of briefs.
- (c) The presiding officer may reopen the record to receive further evidence at any time before the filing of the initial decision.

§ 12.105 Examination of record.

Documents in the record will be publicly available in accordance with §10.20(j). Documents available for examination or copying will be placed on public display in the office of the Division of Dockets Management promptly upon receipt in that office.

Subpart G—Initial and Final Decisions

§ 12.120 Initial decision.

- (a) The presiding officer shall prepare and file an initial decision as soon as possible after the filing of briefs and oral argument.
- (b) The initial decision must contain—
- (1) Findings of fact based issued upon relevant, material, and reliable evidence of record:
 - (2) Conclusions of law;
- (3) A discussion of the reasons for the findings and conclusions, including a discussion of the significant contentions made by any participant;
- (4) Citations to the record supporting the findings and conclusions;
- (5) An appropriate regulation or order supported by substantial evidence of record and based upon the findings of fact and conclusions of law; and
- (6) An effective date for the regulation or order.
- (c) The initial decision must refrain from disclosing specific details of matters specified in $\S 10.20(j)(2)(i)$ (a) and (b), except as specifically authorized in a protective order issued pursuant to $\S 10.20(j)(3)$.
- (d) The initial decision is to be filed with the Division of Dockets Management and served upon all participants. Once the initial decision is filed with the Division of Dockets Management, the presiding officer has no further jurisdiction over the matter, and any motions or requests filed with the Divi-

- sion of Dockets Management will be decided by the Commissioner.
- (e) The initial decision becomes the final decision of the Commissioner by operation of law unless a participant files exceptions with the Division of Dockets Management under §12.125(a) or the Commissioner files a notice of review under §12.125(f).
- (f) Notice that an initial decision has become the decision of the Commissioner without appeal to or review by the Commissioner will be published in the FEDERAL REGISTER, or the Commissioner may publish the decision when it is of widespread interest.

§ 12.125 Appeal from or review of initial decision.

- (a) A participant may appeal an initial decision to the Commissioner by filing exceptions with the Division of Dockets Management, and serving them on the other participants, within 60 days of the date of the initial decision.
- (b) Exceptions must specifically identify alleged errors in the findings of fact or conclusions of law in the initial decision, and provide supporting citations to the record. Oral argument before the Commissioner may be requested in the exceptions.
- (c) Any reply to the exceptions is to be filed and served within 60 days of the end of the period for filing exceptions.
- (d) The Commissioner may extend the time for filing exceptions under paragraph (a) of this section or replies to exceptions under paragraph (c) of this section only upon a showing by a participant of extraordinary circumstances. Such an extension shall be requested by filing a written request with the Commissioner's Executive Secretariat (HF-40) and serving copies of the request on the Division of Dockets Management (HFA-305), the Chief Counsel (GCF-1), and all hearing participants.
- (e) If the Commissioner decides to hear oral argument, the participants will be informed of the date, time, and place, the amount of time allotted to each participant, and the issues to be addressed.
- (f) Within 10 days following the expiration of the time for filing exceptions